NIH POLICY MANUAL

6315-1 - REVIEW AND EVALUATION OF R&D CONTRACT PROPOSALS

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A. Purpose:

This chapter presents policies and procedures for the review, evaluation, negotiation, and award of NIH biomedical and behavioral research and development (R&D) contract projects. It applies to all contract projects for the conduct of R&D and/or the direct support of the conduct of R&D, including innovative testing, research, demonstration, and related efforts. The term R&D includes research, development, demonstration and R&D support. (See Section C for definition) This chapter supplements the Health and Human Services Acquisition Regulations (HHSAR 315.6).

It does not apply, to contracts for purposes incidentally related to R&D, i.e., non-R&D, such as:

The routine purchase of commercially available items sold in substantial quantities to the general public with published price lists, etc., i.e., "off-the-shelf", laboratory or general equipment, materials, supplies, animals, or routine services for R&D projects;

The conduct of program evaluations, public or technical information services or clearinghouses, scientific conference or logistics support, or other services not directly performing nor directly supporting R&D; nor

The performance of minor enhancements to existing equipment or systems.

B. Background and References:

Thorough, competent scientific, technical and business review and evaluation of biomedical and behavioral R&D contract projects constitute essential features of the contracting process, serving to:

promote optimal selection of projects to accomplish high priority NIH program needs; engender competition among qualified offerors; establish technical ranking of proposals; specify technical and business issues, e.g., strengths and weaknesses, to enable meaningful technical and cost discussions; and promote submission of optimal best and final offers from both technical and cost standpoints.

All these functions facilitate decision-making for selection of projects and sources that offer the greatest benefits to the Government, and thus contribute towards fulfilling identified NIH needs and requirements for R&D contract awards. Several references provide background for this issuance:

1. Public Health Service Act as amended, December 31, 1987, Sections 405. and 492.
2. Title 48 of the Code of Federal Regulations (48 CFR), Federal Acquisition Regulation, (FAR), Part 15 (48 CFR 15), Contracting by Negotiation. FAR Part 35, Research and Development Contracting
3. FAR Subsection, 48 CFR 15.406-1, Uniform Contract Format
4. HHS Acquisition Regulation (HHSAR), 48 CFR 315, Contracting by Negotiation
5. HHS Regulations, 45 CFR, Part 11, Committee Management
6. Public Health Service Regulations, 42 CFR Part 52h, Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects.
7. NIH Manual 1805, Use of Advisors in Program and Project Review and Management.
8. NIH Manual 1810, Procedures for Avoiding Conflict of Interest for NIH Advisory Committee Members and Ad Hoc Consultants (Formerly NIH Manual 2300-735-2). Pending Release.
9. NIH Manual 1825, Information Collection from the Public
10. NIH Manual 26307-1/6307-1 Organization of Contracting Responsibilities
11. NIH Manual 6015-1, Cost Analysis of Research and Development Proposals (still issued as 6000-3-03.807)
12. NIH Program Administrators' Handbook, 1990. DHHS Project Officers' Contracting Handbook, NIH Edition
13. I&I Memoranda OER 90-5 and DCG 90-5, Inclusion of Minorities and Women in Study Populations
14. I&I Memorandum OD 90-1, Conflict of Interest and Confidentiality Certifications for Evaluations of Grant and Cooperative Agreement Applications, Contract and Subcontract Proposals, and Active Projects. (NIH Manual 1805)
15. I&I Memorandum OER 91-01/DCG 91-2, Procurement Integrity Act (PIA), Conflict of Interest and Confidentiality Certification Implications for Individuals Evaluating the Scientific and Technical Merit of NIH Contract Proposals. (NIH Manual 1805, 6315-1)

C. Definitions (listed alphabetically):

(See also 42 CFR 52h.2 and NIH Manual 26307-1/6307-1.)

1. Acceptable Proposal

   A proposal judged by the majority of a technical evaluation group (TEG) to be complete in itself, to contain no major deficiencies, and to present sufficient evidence to indicate that the offeror is capable of satisfying the minimum requirements of the Request for

Proposal (RFP) and is thus eligible for consideration for (a) inclusion in a competitive range for a competitive acquisition or (b) award in the case of a noncompetitive acquisition.

2. Competitive Range

   All proposals which have a reasonable chance of being selected for final award after the subsequent conduct of written or oral discussions concerning technical, price and other factors.

3. Evaluators

   Any individuals, including Government employees, who participate in scientific or technical merit reviews/evaluations of contract or subcontract proposals, or active projects under the NIH awards, and who assign scores or ratings, or make funding recommendations. This includes members of Technical Evaluation Groups, Source Evaluation Panels and Source Selection Panels or Participants in these evaluation steps in the acquisition process. While employees who carry out administrative and programmatic duties associated with the review process are excluded from this definition, they must, however, abide by the conflict of interest regulations specified in 45 CFR Part 73, Standards of Conduct, as well as Confidentiality of Information and Procurement Integrity regulations. Thus, at key points in the acquisition process, evaluators are critical participants on Program Advisory Groups, Technical Evaluation Groups, Source Evaluation Panels and Source Selection Panels as defined above.

4. Program Advisory Group (PAG)

   A peer review group which reviews and approves or disapproves concepts for R&D contract projects.

5. Research and Development (R&D)

   Research, development, and demonstration activities typically involve procedures to acquire and apply new scientific knowledge and to:

   develop approaches and methodology; perform experimental procedures; record observations and data; analyze and interpret findings; and publish results, interpretations, and conclusions.

   The spectrum of biomedical and behavioral research, development, demonstration, and R&D support activities are defined as follows:

   a. Research

   Systematic search or intensive study directed towards achieving new or fuller scientific knowledge or understanding beyond the state of the art, and/or towards the practical application of knowledge/understanding to advance specific program objectives.

b. Development

Systematic use of knowledge and understanding gained from research, directed towards creating useful materials, devices, systems, or methods to meet functional or economic feasibility requirements, including procedures to accomplish significant novel enhancements to existing equipment or systems.

c. Demonstration

Systematic studies of the feasibility of disseminating or applying R&D findings to community or other group situations, e.g., establish effectiveness of health diagnosis, treatment, or prevention approaches to improve public health.

d. R&D Support

Procedures, techniques, and activities directly supporting the conduct of R&D, involving innovative or standard methodologies to prepare or provide special materials, resources, or services integral to performing R&D projects, e.g., screen or test components for biological activity; collect, provide, analyze, or interpret experimental research data or information, or provide significant enhancements to existing equipment or systems.

6. R&D Contract Project

   An identified, circumscribed R&D activity encompassing the project concept and approach; the project may involve a single contract or two or more similar, related, and interdependent contracts encompassing the project concept and approach. The term includes R&D contracts to perform research, develop and utilize R&D resources, test new materials or systems, conduct clinical trials and demonstrations, prepare innovative reports, and produce experimental or test models or materials necessary or integral to performing a research and/or development project; the term excludes quantity production and routine product testing and quality control when not performed in direct support of R&D as defined.

7. R&D Contract Proposal

   A written offer to enter into a contract, submitted to an awarding official by an individual or non-Federal organization, usually in response to a request for proposals (RFP), and including as a minimum a description of the nature, purpose, duration, and cost of the project and the methods, personnel and facilities to be utilized in carrying it out. It consists of a technical proposal and a business proposal.

8. R&D Project Approach

   The methodology to be followed and resources needed to carry out the R&D project.

9. R&D Project Concept

The basic purpose, scope, and objectives of the project. The scope may include estimates of the total costs and time needed for the project.

10. Scientific Review Administrator (SRA)

    The NIH official who has the responsibility to ensure that contract proposals receive a competent, thorough and fair peer review by a Technical Evaluation Group, consistent with all relevant NIH review policies. The previous title of the SRA was Executive Secretary. The SRA organizes and provides scientific/technical support to a TEG, and is responsible for the contents of TEG minutes, including votes on acceptability or unacceptability and scoring of proposals, and other recommendations, to the Project Officer and Contracting Officer.

    For evaluation or reviews not involving TEGs, other terms such as "Official in Charge of Review (OICR)," "recorder," or "executive secretary" may be used for similar functions.

11. Scientific-Technical Peer Review Group

    A group of experts qualified by training and experience in particular scientific or technical fields to give expert advice on the scientific and technical merits of contract projects in those fields. The Peer Review Group (1) gives expert advice, approval or disapproval, and other recommendations about R&D contract project concepts, when serving as a program advisory group (PAG) or (2) gives expert advice, votes on acceptability or unacceptability, and gives other recommendations about R&D contract project proposals, when serving as a technical evaluation group (TEG). Not more than one-fourth of the Peer Review Group to which this policy is applicable may be officers or employees of the United States. For purposes of the preceding sentence, membership on such groups does not make an individual an officer or employee of the United States.

    ICD staff are ineligible to participate as members or Scientific Review Administrators (executive secretaries, recorders) of scientific or technical peer review groups evaluating and recommending on specific contract proposals or projects, for which they have had or may have other selection, award, or administration responsibilities. ICD staff may serve as policy or technical resources to the PAG.

12. Source Evaluation Panel (SEP)

    A generic term for an ICD committee which evaluates the technical evaluation group recommendations and develops questions to offerors based on identified weaknesses in their proposals. The SEP should comprise, at a minimum, the project and contracting officers, and should be supplemented by at least one other person with appropriate technical expertise. The SRA of the TEG may participate as a non-voting member.

13. Source Selection Panel (SSP)

    A generic term for an ICD committee which evaluates the best and final offers and recommends to the CO the offeror(s) who should receive an award(s). The SSP should

comprise, at a minimum, the project and contracting officers, and should be supplemented by at least one other person with appropriate technical expertise.

14. Technical Evaluation Group (TEG)

    A review group which provides scientific and technical review and evaluation of proposals for R&D contracts.

15. Unacceptable Proposal

    A proposal judged by a TEG majority to have failed to demonstrate the offeror's ability to satisfy the minimum requirements of the RFP without significant revisions, and to have deficiencies so substantial as to preclude any possibility of considering it for (a) inclusion in a competitive range for a competitive acquisition or (b) award in the case of a noncompetitive acquisition.

D. Policy:

NIH requires competent, objective, and expeditious evaluation of biomedical and behavioral R&D contract projects, conducted by qualified reviewers. Procedures implementing this policy aim to ensure optimal selection of contract projects, based on established program priorities and needs, maximal opportunities for equitable competition, and the award of contracts to sources most likely to achieve NIH objectives at a fair and reasonable cost, within existing structures of applicable statute and regulation requirements. All biomedical and behavioral R&D contract projects require scientific-technical peer review and approval of both concepts and proposals before contracts may be awarded, contracts may be awarded, regardless of whether they originate from extramural or intramural program requirements.
Discussion:

Scientific-technical peer review of R&D contract project concepts identifies the basic purpose, scope, and objectives of the projects and establishes relevance, priority, and need of projects to accomplish NIH program objectives.

Scientific-technical peer review of R&D contract proposals provides objective evaluation of technical aspects and acceptability or nonacceptability of specific proposals based on the requirements stated in the request for proposal (RFP), and helps ensure achievement of program goals by identifying the best technically qualified offerors.

The review of R&D contract proposals shall be conducted in a manner consistent with the standards of quality in the system for technical and scientific peer review that is applicable to NIH grant applications for biomedical and behavioral research.

Evaluation of business proposals determines the reasonableness of cost elements and management capabilities of offerors to perform the required work.

Subsequent staff reviews (including source evaluation panels and source selection panels) and discussions and negotiations with offerors aim to select contractors most capable of accomplishing stated requirements to the best possible advantage to the NIH.

NIH staff responsible for accomplishing these reviews should use full and open competition, when possible, and ensure that reviews are performed in such a manner as to provide for the most competent advice to guide official decisions on selection and award of contractors as prescribed by acquisition regulations. At all times in the process, staff seek to avoid actual or apparent conflicts of interest, to maintain confidentiality of information, and to obtain compliance with procurement integrity requirements.

Appendix 1 shows the steps in the process from project development through contract award.

E. Responsibilities:

1. The Associate Director for Extramural Affairs, NIH, establishes NIH policies and procedures for scientific-technical reviews and evaluations of R&D contract projects, and determines the adequacy of procedures implementing those principles.

2. The Director, Division of Contracts and Grants, OA, establishes NIH policies and procedures for business-administrative reviews, evaluations, and awards for R&D contract projects, in accordance with requirements established in the FAR, HHS and PHS Acquisition Regulations and determines the adequacy of procedures implementing those principles.

3. Directors of awarding institutes, centers, and divisions (ICDs) ensure adherence within their organizations to established NIH policies, and maintain adequate communications between program, contracting, and review staffs.

4. Senior ICD program, review, and contracting officials supervise and oversee contracting activities and are responsible for ensuring the adequacy of scientific peer review and evaluation of R&D contract projects and proposals in their awarding components.

5. Contracting officers (COs) collaborate with project officers to develop Acquisition Plan/Request for Contract (AP/RFC) documents for R&D contracts, conduct administrative/business reviews of contract proposals, monitor and assist technical evaluations and documentation to ensure compliance with acquisition regulations, set the competitive range based on SEP recommendations, and select and award R&D contracts based on established requirements and results of appropriate reviews and evaluations. (See also FAR and HHSAR references in B., above.)

6. Project officers (POs) collaborate with COs to develop AP/RFCs, provide program information for R&D project concept and proposal reviews, serve as a resource regarding scientific aspects and summarize the background an objectives of the RFP to ensure the Technical Evaluation Group's understanding of the intent of the RFP, and advise contracting officers regarding technical aspects of competitive range discussions and final negotiations.(See also, DHHS Project Officers' Contracting Handbook, NIH Edition.)

7. Scientific Review Administrators (SRAs) establish and supervise competent and equitable scientific-technical reviews and evaluations for R&D contract proposals. They ensure also that review group members have no real or apparent conflicts of interest to

preclude their participating in the review of proposals in a given competition and assure that Conflict of Interest, Confidentiality of Information and Procurement Integrity Act certifications have been signed and are submitted. They interact with POs and COs as necessary to understand the review requirements of the acquisition, including providing advice on evaluation criteria during AP/RFC development. They are responsible for providing documentation of the TEG review to the Contracting Officer and Project Officer. (See NIH Manual 1805)

F. Procedures: Acquisition through Full and Open Competition:

1. Presolicitation Procedures

   Presolicitation R&D contracting procedures include interactions by program, contracting, and review staffs to:

develop the project concept; obtain scientific peer review of the concept to establish relevance, priority, and need; develop the AP/RFC as an omnibus, planning and requisitioning document; and prepare a request for proposal (RFP), which describes the Government's needs, soliciting prospective offerors to submit a proposal based on a framework of specific requirements, terms and conditions, often seeking innovative and original approaches to accomplish the tasks described in the RFP.

a. Project Concept

PHS Scientific Peer Review regulations require that scientific peer review of each R&D contract project concept be obtained before issuing a request for proposals. (42 CFR 52h.10) The concept identifies the basic purpose, scope and objectives of the project.

Timely project concept reviews are required for all R&D contract projects as defined at 52h.2(h), and above at C.

R&D project concepts are developed usually by program staff based on prior discussions with advisory groups and other interactions with the scientific community. The concepts are evaluated by ICD procedures before beginning the acquisition process.

If ICD staff cannot easily judge whether a given contract project belongs in the R&D category, they should choose the course of peer review to ensure a broad base of expert advice and justification for contract awards.

Before issuing an RFP, the CO ensures that the project concept has been reviewed and approved by a scientific peer review group in accordance with requirements of 42 CFR 52h; under certain circumstances, the R&D project concept review may be deferred (See a.2 below).

Title 42 CFR 52h and NIH Manual 1805, F.1.b., restrict awarding ICD staff from functioning as members or SRAs or executive secretaries of advisory scientific or technical group reviews (PAG, or TEG) concerning contract projects or proposals for

which they have had or may have other selection, award, or administration responsibilities. The Project Officer may not serve as SRA (or PAG executive secretary) or prepare the summary minutes for R&D concept reviews.

(1) Recommendations

Program Advisory Group recommendations must address concepts for specific projects rather than broad program activities. When contract project concepts are to be reviewed, program staff responsible for those reviews should make clear to participating advisors that the awarding component seeks their advice with respect to the project(s) anticipated.

(2) Waiver (deferral) of Presolicition peer review to enable issuance of an RFP.

The awarding ICD Director or designee may waive (defer) the presolicitation peer review of a project concept when such a waiver is necessary, in the best interests of the Government, to accomplish essential program objectives, or achieve significant time, effort, and/or cost savings. Thus, concept peer reviews might reasonably be delayed for such acquisitions as small dollar projects, e.g., under $100,000, and recompetitions and extensions of current projects where previous peer review has established the validity of their concepts and no major changes have occurred in the scope of work or the state-of-the-art of the project content. When presolicitation concept review is waived, the Director or designee shall document the basis for that determination, and the RFP shall indicate that the project concept has not been reviewed by a peer review group and that no award will be made until such a concept review is conducted before the proposal(s) are reviewed and recommendations made based on such review. Under such circumstances, the awarding official will not award a contract based on the RFP unless the proposals received in response to the request have been reviewed by a peer review group and that group has approved the scientific merit of the project concept and approaches outlined in the proposals. (42 CFR 52h.10(b)).

NIH prefers that different peer review groups review project concepts and proposals.

(3) Exclusions

The ICD Director or designee may determine and document to the CO that project concept peer review is not needed in these circumstances:

(a) When the solicitation is to recompete or extend current projects, previous peer review has established the validity of the concepts, and no major changes have occurred in the project's scope of work or in the state of art of the project's content, concept peer review is not needed.

(b) Congressional authorization or mandates for awarding components to accomplish certain contract projects are sufficient authority for the

components to pursue those activities without additional advisory inputs, e.g., "The Director of the Institute shall...establish the National Diabetes Information Clearinghouse..." The Congressional intent must be expressed for specific projects, rather than for program wide activities as in "The Director of the Institute shall conduct and support research into spinal cord regeneration."

(c) When projects are not for the actual conduct or direct support of R&D activities, concept peer review is not needed. Examples include: breeding or holding facilities for animals before they become involved in experimentation; scientific conferences to exchange information on R&D fields or results; or purchases of commercially available supplies, services, animals, and the like.

(d) Project concept peer reviews are not needed for evaluation projects to assess productivity, impact, or quality of NIH programs, when those projects have been reviewed by the NIH Evaluation Project Technical Merit Review Committee.

(4) Project Concept Reviews

Awarding components may review project concepts by various appropriate means, including chartered program and policy advisory committees, ad hoc advisory groups for specific program areas, or seminars, conferences, workshops, and the like, whenever these meet the definition and composition requirements of "peer review group" in 42 CFR 52h. (See also NIH Manual 1805) Program staff responsible for those reviews shall make clear to participating advisors that the awarding component seeks their advice with respect to the anticipated project(s). When necessary, concept reviews may be conducted by mail or teleconferences.

In all cases, a specific concept should be presented for approval, with corresponding background and rationale (estimated total costs may be included), and be reflected in formal concept review minutes, which include the vote for approval or disapproval.

(5) Concept Review Considerations

Concept review groups shall consider features of the purpose, scope and objectives which are specific to each R&D project, including:

scientific, technical, or program significance of the goals of the proposed R&D activity;

availability of the technology and other resources necessary to achieve the required goals;

extent to which identified, practical scientific or clinical uses exist for the

anticipated results; and

where the concept review includes the project approach, the adequacy of the methodology to be used in performing the activity. (Note: conflict of interest regulations apply in this case) See also (6) below.

attention to ensure the adequacy of inclusion of women and minorities in clinical research, if applicable (I&I OER 90-5 and DCG 90-5).

R&D project concept reviews may encompass two levels of discussion:

a. general project purposes, scopes, and goals, and various optional approaches to obtain required results, consistent with "project concept" as defined; or

b. in addition to a), specific details of projects or RFPs, e.g., selecting technical approaches, developing specific protocols or work statements, or establishing data formats or product specifications, as for "project approach" as defined. In this case, members act as Procurement officials and are also subject to conflict of interest and PIA regulations (See (6) below)

(6) Meetings

Insofar as possible, attendance at concept review meetings will include contracting and review staff appropriate to the projects under discussion, as well as program staff responsible for program presentations and subsequent project management.

Concept review meetings are generally open to the public. Persons who attend or participate in meetings as in (5)a) above will be eligible to receive contract awards resulting from subsequent RFPs, unless other factors contravene.

When concept review occurs using alternatives to chartered committees, every attempt should be made to ensure the opportunity for open discussion consistent with these procedures.

However, sessions which review specific details of projects or RFPs, as in (5)b) above, will be closed to the public, under authority of 45 CFR 11.5(a) (6) (ii) (c), to protect the free exchange of advisory group members' opinions and avoid undue interference with NIH operations. In those situations, participating reviewers and attendees shall be notified in advance that, under 42 CFR 52h.5(b) (3), dealing with conflict of interest, they, their close relatives and professional associates, and their organizations, will be ineligible to receive awards resulting from subsequent RFPs, and that the Procurement Integrity Act requirements apply.

Consistent with 42 CFR 52h.5(c), the Director, NIH may waive (dispense with) this ineligibility restriction upon adequate written justification from the awarding component Director. The justification should allow the Director to determine that there is no other practical means for securing appropriate expert advice on a particular contract project or contract proposal. The justification shall be submitted prior to the concept review, whenever feasible.

Appendix 2 presents examples of announcements that the advisory group chairperson should make at the start of the concept review meeting.

(7) Documentation

Program staff of the awarding ICD organization shall document concept reviews with summaries of staff presentations and advisory group opinions and recommendations for approval; these summaries shall become part of official contract files.

(8) Once concept approval is obtained from the peer review group, all communications must be handled only by the contracting officer or designee.

b. Acquisition Plan/Request for Contract (AP/RFC)

This document constitutes appropriate approval and authorization of acquisition, allowing issuance of an RFP, and future obligation of funds, according to awarding component procedures.

Preparation of the AP/RFC is the responsibility of program staff assisted by contracting and review staff as needed. It contains all information needed to prepare the RFP and therefore must be written so as to ensure that the RFP will be clear, complete, and likely to engender effective maximum competition. The statement of work and technical evaluation criteria, in particular, must reflect those considerations.

An AP/RFC contains all documentation used for concept clearance and a schedule of milestones for postsolicitation review and award phases. (See Appendix 1) Information elements to be included in the AP/RFC are set forth in HHSAR 307.1. These requirements have been combined into a format for NIH research contracting activities use, and appear in I&I Memorandum DCG 90-6 (Rev. 1).

Depending on dollar thresholds, additional presolicitation reviews by the DCG, OA and the EPMO, OER, are required prior to issuance of an RFP. Organizational ICD components responsible for review of proposals should be included in the process of developing technical evaluation criteria in order to identify ambiguities, inconsistencies or appropriateness of the criteria, in relation to the statement of work, which may affect the review process.

c. Request for Proposals (RFPs)

Final presolicitation steps are the CO's preparation and public of the RFP, assisted by program staff.

The RFP must describe as specifically and precisely as possible:

the work or services to be performed;

the terms. conditions, and provisions that will form the basis for final definitive contracts; and

the specific evaluation criteria, including their relative importance or weight to guide offerors in preparing proposals and the technical evaluation groups in evaluating proposals.

(1) Statement of Work

The RFP work statement includes specifics of the project from the AP/RFC that will enable offerors to respond in appropriate and competitive manner to the RFP. Minimum mandatory qualifications or special contractor responsibility or qualifications standards, e.g., restrictions limiting offerors to those within a certain geographical radius or time requirement, are viewed with concern because they restrict competition; such restrictions should therefore be weighed carefully and must be approved as part of the RFC. The RFP must explain for potential offerors the rationale for the restriction.

(2) Data

RFP Section L, Instructions, Conditions, and Notice said Offerors, informs prospective offerors that the proposal must be prepared in two parts: a technical and a business proposal, each separate and complete in itself so that evaluation of each may be performed independently of, and concurrently with, the other. Technical proposals must include proposed direct cost and resource information such as labor categories, labor hours, direct labor rates, materials, travel, proposed subcontracts, computer time, etc., but must exclude indirect costs and fees. Technical proposals shall be submitted to technical reviewers for evaluation.

Awards of R&D contracts are generally influenced primarily by technical rather than cost or price, as discussed in the RFP. The aim is to identify the most promising and technically sound proposals completing under the RFP. Offerors' estimates of personnel,equipment, facilities and other project costs are helpful indicators of their basic understanding of the RFP requirements.

(3) Award Factors

HHSAR 315.406-5 requires that RFPs clearly inform prospective offerors of the relationship and relative importance of cost or price in comparison to other evaluation criteria. The relationship is expressed generally in one of three ways:

Paramount consideration shall be given to evaluation of technical proposals rather than cost or price (customary for NIH R&D cost reimbursement contracts); or

Paramount consideration shall be given to cost or price rather than technical consideration; or

Equal consideration shall be given to evaluation of technical proposal and cost or price.

(4) Other Considerations

RFPs may allow for submission of alternate proposals, provided the offeror submits a proposal for performance of the RFP statement of work. Alternate proposals may be considered if overall performance would be improved or not compromised, and if they are in the best interests of the NIH.

(5) Publication

A notice of proposed contract action shall be published in the Commerce Business Daily at least 15 days before issuing the solicitation. The contracting activity must allow at least 45 days' response time for receipt of proposals from the date of publication of the notice of contract action, and 30 days after release of the RFP.

The notice of the RFP availability should be published in the NIH Guide for Grants and Contracts whenever possible to encourage full and open competition, especially if it is anticipated that the pool of offerors will include universities.

d. Special Considerations

Special clearances are required before executing certain contracts and these should be considered sufficiently early in the acquisition process so that awards are not delayed immeasurably. Some of these clearances include:

(1) Human Subjects

Contracts involving human subjects require prior clearance in accordance with 45 CFR 46 and NIH Manual 6380-1. It should be noted that these procedures encompass many projects besides clinical trials, and it it is essential to determine if specific projects fall within established requirements.

(2) Animal Welfare

Contracts involving care and use of vertebrate animals may not be awarded until after appropriate clearance consistent with NIH Manual 6380-2. These requirements apply to any animal welfare procedures involved, even if these do

not include research/development per se.

(3) Recombinant DNA

Any contract utilizing recombinant DNA technology requires prior clearance in accordance with provisions of Guidelines for Research Involving recombinant DNA Molecules, in the Federal register, May 7, 1986, vol. 51, #88, pages 16958-16985.

(4) Project Clearance

the collection of survey or other information from ten or more respondents requires prior Office of Management and Budget review and approval, consistent with NIH Manual 1825. (See also 44 U.S.C. Chapter 35, and 5 CFR Part 1320.) When the information collection is for identification or classification of specimens or is from individuals under treatment or clinical examination, however, those projects do not require OMB approval but do require NIH Clinical Exemptions Committee review and approval.

(5) Privacy Act

Whenever the PO determines that the Privacy Act applies to a given contract, current systems must be reviewed and a new one established and cleared as necessary, in accordance with policies and procedures in PHS General Administration Chapter 45-12, "Creation, Alteration, and Termination of Privacy Act Systems of Records and Associated Documentation."

(6) Inclusion of Women and Minorities in Clinical Studies (See I&I OER 90-5 and DCG 90-5).

It is policy of the NIH that offerors for clinical research contracts include women and minorities in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. RFPs will identify when the policy is relevant. If the offeror does not include women/minorities in its proposed study population, or proposes a representative of women and minorities less than that anticipated by the objectives expressed in the Statement of Work, a specific rationale for this exclusion or underrepresentation must be provided. The rationale will be evaluated during the technical peer review of proposals for its appropriateness in terms of the requirements of the acquisition.

(7) Foreign contracts

Contracts with organizations in other countries require prior clearance in accordance with procedures in NIH Manual 6325-1/26101-26-1. The need for both NIH and State Department clearances suggests that additional time be

allowed for foreign contract awards.

2. Pre-Evaluation Procedures

a. Receipt of Proposals

The contracting officer must receive proposals by the closing date and time published in the RFP. this official forwards the technical proposals to program and review staff, ensuring that direct cost data are included, but excluding indirect costs and fees. A transmittal memorandum should convey, at a minimum. a list of offeror organizations and the data for receipt of technical evaluation report, developed with review staff during RFP development. The project officer also receives the business proposal.

The SRA is responsible for controlling distribution and securing all proposals provided for use in the evaluation process. After the TEG meeting all accounted for by returning them to the SRA, disposing of them in a manner that preserves the confidentiality of the material, or filing them in an appropriate manner. Proposals received after the published closing date are treated as Late Proposals, consistent with FAR 15.412 and PHSAR 352.215-1/.

b. Staff Review

Pertinent program staff shall help the SAR and CO examine technical proposals before submitting them to TEG members, to ensure that the proposals are complete.

c. Clarification

Before TEG evaluations, the CO may inquire of offerors to clarify minor irregularities, informalities, or apparent clerical mistakes; these clarifications must be submitted in writing but are not considered "discussions" within the meaning of FAR 15,601/15.610, and do not require similar inquires of all offerors. Clarifications must be restricted to non-substantive matters and must not result in revision of the proposal. If clarifications result in a revision or would otherwise prejudice interests of other offerors, the information should be returned to the offeror without being evaluated, or similar communications should be conducted as appropriate with all offerors.

d. Selection/Approval of Reviewers

Scientific-technical evaluation of biomedical and behavioral R&D contract proposals is the responsibility of review staff organizationally from pertinent program units or operating divisions. Technical evaluation groups (TEGs) must be selected in accordance with committee management, peer review, conflict of interest, and procurement integrity requirements and restrictions.

Each ICD review component shall designate official(s) to supervise technical evaluations of biomedical and behavioral R&D contract proposals. These officials shall have responsibilities to develop and implement their organizations' evaluation procedures,

assign SRAs the responsibilities for managing and conducting technical evaluation of proposals for specific acquisitions, approve ad hoc reviewers, designate presiding officials for ad hoc reviews, and develop procedures to ensure the confidentiality of materials and disposition of documents after reviews. Those officials shall also ensure close communications among review, program, and contract management staffs in order to promote mutual understanding of applicable policies, procedures, practices, philosophies, and goals.

While scientific-technical evaluations are performed by advisors with specific expertise in pertinent scientific disciplines and disease areas, responsibilities for ensuring that evaluations follow review and acquisitions regulations and policy standards rest with the SRAs and COs respectively. POs should discuss project requirements with SRAs to ensure that required disciplines will be represented on evaluation teams. POs should also provide SRAs with names of potential individual reviewers with expertise in the required scientific or technical disciplines. No staff, however, may directly or indirectly solicit names or potential reviewers from a source who is proposing a response to a specific rfp requirement. SRAs are responsible for deciding review group memberships and are the only staff in addition to the CO, and with the CO's concurrence, who may communicate with actual or potential reviewers about the evaluation.

To help ensure the integrity of the evaluation process, before sending, materials, SRAs shall establish that all evaluations have no conflicts of interest with the offeror organizations or investigators and will ensure the confidentiality of technical information, documents, and proceedings. (See I&I OD 90-1 and oer 91-01) They will send statements to be signed and returned immediately by all reviewers, certifying that they have no conflicts of interest in the form of any employment or other professional or personal financial interests in the competing offerors, that they will comply with procurement integrity requirements, that they agree to preserve the confidentiality of the review and will not disclose the contents of proposals to anyone without the express written consent of the CO and SRA.

If a reviewer subsequently identities a conflict of interest, he/she should notify the SRA immediately to determine whether he/she should be disqualified from being a reviewer.

The key review issues concerning reviewers are:

(1) All biomedical and behavioral R&D proposals must be evaluated by scientific-technical peer review groups.

(2) Evaluations may be performed by chartered committees or ad hoc groups. (See references for guiding principles applying to the selection, appointment, and functions of TEG members and their subpanels/subgroups.)

(a) Existing chartered committees with appropriate expertise should be used whenever possible. A chartered committee may not evaluate proposals responding to an RFP, however, whenever any member(s) of that committee, their spouse, parent, child, or close professional associate

is named on a competing proposal as the principal investigator of other staff responsible for conducting the project. Ad hoc groups may be used when necessary to achieve functions but not one ad hoc group may be used on a continuing basis. As hoc groups must also have more that 50% non-committee membership, and the chairperson of the chartered committee may not be a committee member.

(b) With ICD Director, or delegated official, approval, reviews may be performed by mail or teleconference using standard review and documentation procedures for individual evaluations (without consensus).

(c) NIH Reviewers Reserve members may serve on chartered committees with full rights, and privileges and obligations of appointed members, including voting and assigning priority ratings if they are present for the entire meeting; however, they do not count towards a quorum.

(d) Reviewers shall sign certifications to comply with Conflicts of Interest, Confidentiality of Information and Procurement Integrity Act requirements (I&I OD 90-1; I&I OER 91-01).

(e) Ad hoc consultants in chartered committee meetings may present and discuss opinions and contribute otherwise to the proceedings, but may not vote on committee actions regarding acceptability or ratings proposals.

(f) No reviewer may participate in an evaluation, who submitted or is closely associated with an individual or organization that submitted a competitive proposal responding to the RFP. It may thus be necessary to delay final selections of reviewers until the complete list of offerors is known.

e. Orienting/Briefing Reviewers

To aid in evaluations, review staff provide appropriate background documents to TEG members to help them understand the program, relevance, and rationale for the solicitation. These materials may include relevant portions of the project plan or comparable presolicitation documents; summary reports of relevant staff and concept reviews; and technical portions of the RFP, including especially the statement of work and technical proposal instructions, evaluation criteria, and other program information.

The SRA and CO must ensure that all TEG members understand their roles and responsibilities in the competitive acquisition process, by providing written guidance emphasizing:

role or peer review in the acquisition process; judgement of each proposal independently based solely on the evaluation criteria reflecting the statement of work; restriction of evaluations to the specific solicitation and contents of the written proposals; evaluation of all proposals by all TEG members; identification

of proposals' ambiguities, inconsistencies, deficiencies, and errors the role of reviewers in providing documentation of individual strengths and weaknesses of each proposal in accordance with each evaluation criterion; confidentiality of review materials and deliberations; adherence to conflict of interest and procurement integrity regulations/policies; and the NIH policy on inclusion of minorities and women in clinical studies, when relevant.

SRAs shall also caution reviewers that, since the RFP work statement already embodies prior peer-reviewed considerations of relevance, need, priority, and scientific/clinical rationale, their evaluations should not involve those factors. SRAs/COs should also mention the competitive range process so that reviewers understand how their evaluations interrelate with subsequent procedures.

3. Technical Evaluation

The selected TEG peer reviewers perform the scientific-technical evaluations of all proposals in response to an RFP, guided by the SRA. POs, COs, and other staff should attend scientific-technical evaluation group meetings reviewing proposals within their respective responsibilities, so they may provide all technical, administrative, and program information essential for adequate review and evaluation. They may not, however, join the scientific-technical discussions and recommendations concerning those proposals. All staff must avoid evaluative comments or indications of bias towards individual offerors or proposals.

a. Contracting Officer

The CO or representative, e.g., contract specialist, must be present at all R&D proposal technical evaluations. That official should address the TEG meeting, as necessary, and serve as a resource concerning applicable regulations and policies, and confirm that recommendations and scores reflect the tone of the discussion.

b. Scientific Review Administrator

The SRA must ensure that TEG members address all proposals and factors impartially and completely, basing their evaluations on proposals as submitted, and clarified by the CO as appropriate. TEG questions regarding scientific review should be addressed to the SRA, and questions on contract policy are addressed to the CO or designee. The SRA ensures that recommendations and scores reflect the tone of the discussion.

c. Project Officer

The PO or representative participates to summarize briefly the program background and purposes for the RFP and results desired from the contract; this should be done before any specific proposals are reviewed. The PO serves also as a resource to explain programmatic points that TEG members may raise during the evaluation concerning the solicitation or contract.

d. Technical Evaluation Group Members

Prior to the meeting, all technical evaluators individually examine and evaluate all proposals and determine strengths and deficiencies relevant to the RFP evaluation criteria, which serve as the standard against which all proposals responding to the RFP are evaluated. For each proposal, the TEG member may assign a preliminary score for each evaluation criterion guided by the acquisition objectives and the statement of work. Comparisons between proposals are not permitted. Topics for special consideration include concept reviews if not obtained previously, involvement of human subjects, care and use of animals, biohazard protection, inclusion of women and minorities in clinical research, and contents of surveys/questionnaires.

At the evaluation meeting, preliminary assessments serve as bases for discussing technical merits of the proposals. Primary reviewers present narrative descriptions and critiques for each proposal assigned them, assessing strengths and weaknesses in relation to each evaluation criterion, as well as identifying ambiguities, inconsistencies, deficiencies, and errors in the proposals. Other reviewers comment on and discuss their evaluations.

Technical evaluators may provide recommendations regarding offerors' direct cost proposals in certain judgmental cost areas, e.g., hours in specific staffing categories or needs for specific supplies or equipment, and their recommendations are included in technical evaluation summaries regarding proposal strengths and weaknesses. When reviewers express concerns regarding aspects of direct cost estimates, such concerns should be identified and discussed in the summary report to alert the CO and program staff to potential issues that should be raised in the business review and negotiation phases.

If sudden exigencies prevent any TEG member(s) from attending, they should be encouraged to submit written comments, using available physical or electronic means to provide their opinions to the meeting. Those members may not contribute final votes for acceptability or scoring, however.

After general discussion, all TEG members present individually score each proposal on all evaluation criteria, based o corresponding weights announced in the RFP, and refine their comments on specific strengths and weaknesses for all evaluation criteria, reflecting his/her written judgments of strengths or weaknesses derived from the discussion. The evaluators sign and submit their comments and the corresponding score sheets, and evaluation summaries, which are retained as parts of the contract file. The specific format for documentation may vary across ICDs.

When reviewers participate by teleconference, they will be permitted to vote (in private) and score proposals (in private) and will submit their individual evaluations, recommendations, votes and scores by mail, electronic means, or fax. Results of their vote are recorded by the SRA and documented in the review minutes.

e. Acceptability

The final TEG meeting tasks are to determine the technical acceptability and rankings of proposals. If an offeror's proposal indicates sufficient technical understanding and capabilities the members should recommend that it is acceptable. If, on the other hand, the proposal demonstrates a significant lack of understanding or capability to accomplish required tasks, it should be considered unacceptable. The potential for correcting minor deficiencies identified by the TEG must be considered; major revisions of proposals must not be necessary, however, nor may predetermined cut-off scores be used.

A chartered TEG committee may vote as a group on acceptability, but must still provide individual members' written comments and determinations on acceptability. An ad hoc TEG may not vote as a group on acceptability of a proposal, but must provide the individual members' written comments and determination on acceptance as described in d. above. For ad hoc TE s, the SRA includes the ranking in the summary report. Following the acceptability and ranking determinations, the technical evaluators' tasks are co pleted.

f. Technical Rankings

TEG members then rank the proposals; generally, but not necessarily, ranking is accomplished by totaling the numerical scores from all evaluators for the evaluation criteria and calculating average ratings for each offeror. The SRA and/or CO checks each rating sheet for completeness and totals the scores for each proposal. These total scores are displayed during the TEG meeting, and the SRA or CO develops a composite technical ranking.

g. Technical Evaluation Reports

The SRA is responsible for the report and shall prepare technical evaluation summaries for all proposals, documenting strengths and weaknesses, on a criterion by criterion and overall basis. The documente weaknesses and recommendations will serve as a basis for subsequent discussions with those offerors in the competitive range. The reports reflect rankings and scores of each proposal and identify each as acceptable or unacceptable.

Careful preparation of evaluation reports is important since the information will be used later by program and contracting staffs as bases for developing negotiation strategies and for debriefing unsuccessful offerors.

The technical evaluation reports shall be signed by the SRA and verified by at least one TEG member. The original reports and any appendices containing discussion questions shall be delivered to the CO, with a copy to the PO.

4. Business Evaluation

Business evaluation, including cost analysis, of proposals occurs to some degree in each step of the technical review, competitive range, source selection, and final negotiation

processes. (See HHSAR 315.608-7, and NIH Manual 6015-1.

5. Competitive Range

a. Source Evaluation

Following receipt of the technical evaluation summaries from review staff, the CO and/or PO coordinates the selection of a Source Evaluation Panel (SEP), including who will prepare summary minutes of the SEP discussions. The SEP should include relevant technical expertise not directly connected with the procurement.

The SEP confirms proposal strengths and weaknesses noted in the technical evaluation summaries, and identifies ambiguities, inconsistencies, deficiencies, errors, and additional program-based issues, which should be addressed in discussions with specific offerors in the competitive range.

Based on factors discussed above, the SEP may recommend to the CO which offerors should be included in the competitive range, from among those proposals judged acceptable by the TEG.

It must be recognized that only proposals judged acceptable by the majority of a scientific-technical peer review group may be considered for award as R&D contracts. In the rare case that an SEP identifies significant actual or apparent biases, inaccuracies, or errors in the previous TEG evaluation, it may document those deficiencies and recommend that the CO obtain further scientific peer evaluation of all proposals, preferably by the group that reviewed the proposals originally, to see if the initial TEG evaluation concerns were valid. If significant bias is an issue, a new TEG may be necessary to obtain an unbiased review. Any resulting delays in the procurement may result in the need for a Justification for Other Than Full and Open Competition (JOFOC) extension of ongoing projects until a new award(s) is possible, or in the need to obtain extension of the offeror's proposals.

In exceptional circumstances, a proposal deemed unacceptable by peer reviewers may be considered for award by an awarding unit so long as it is or has been documented that some premise or assumption by the reviewers was based on actual or perceived inaccuracies, biases, or errors in the review process. However, in those cases, the proposal must be reconsidered and determined to be acceptable by a scientific-technical peer evaluation group if it is to be considered for award.

Depending on the nature of items to be discussed, the SEP may also recommend site visits at the offerors' facilities (see below).

b. Establishing Competitive Range

Based on the recommendations made during the source evaluation process or by the SEP, the CO determines which proposals are in the competitive range. (See reference FAR 15.609)

Acceptable proposals must be included in the competitive range unless there is no real possibility that they could be improved to the point where they become the most acceptable.

The CO prepares a written competitive range determination based on review findings and program staff advice, and provides a complete rationale for decisions to include or exclude specific proposals from the range. (See FAR 15.609) The CO thereupon notifies offerors excluded from the range and advises them that no discussions or negotiations will be undertaken with them regarding their unsuccessful proposals and that modifications to their proposals cannot be accepted.

c. Technical and Business Discussions

Contracting officers or authorized representatives, supported by program officials and necessary cost analysts, attorneys, etc., as necessary, conduct discussions with offerors whose proposals are within the competitive range. To provide continuity in the process, TEG members may assist in competitive range discussions and subsequent evaluations, as appropriate.

If discussions are held with any offeror in the competitive range, they must be held with all in the range.

Site visits are considered as included within the technical and business discussions (see d, below) and generally involve oral discussions.

Discussions aim primarily to identify proposal deficiencies and ambiguities, improve their clarity from both technical and cost standpoints, and eliminate unnecessarily elaborate provisions exceeding ICD requirements. Discussions must not attempt to improve the quality of proposals up to levels of higher ranking proposals, nor introduce new evaluation elements. The CO shall:

control all discussions;

advise offerors of deficiencies, ambiguities, inconsistencies, errors and other uncertainties of the proposals; and

provide opportunity for offerors to submit technical, cost/price, or other corrections to satisfy the ICD requirements fully.

In those processes, all NIH personnel must avoid:

(1) technical leveling, i.e., helping any offeror bring its proposal up to the level of other proposals by discussing weaknesses resulting from the offeror's lack of diligence, competence, or inventiveness in preparing the proposal;

(2) technical transfusion, i.e., disclosure of technical information from other

proposals, resulting in improvement of a competing proposal; and

(3) auction techniques, e.g.,

(a) indicating a price that an offeror must meet to obtain further consideration;
(b) advising an offeror of its price standing relative to other offerors; or
(c) providing information about offerors' prices.

Discussions shall disclose neither the identity nor the number of offerors, nor provide other details which could give an offeror a competitive advantage. In some acquisitions, more than one round of discussions with all offerors in the competitive range may be required, depending on available time, expense and administrative limitations, and size, complexity, and significance of the acquisition.

When oral discussions are held, i.e., by site visits or telephone, staff must document essential points in the conversations and provide each offeror the opportunity to submit a written response addressing issues from the discussions.

Offerors must be afforded sufficient time to respond to competitive range discussions by submitting revisions to their original offers. When discussions and negotiations are concluding, offerors are requested to submit their "best and final offers" (BAFOs).

All BAFOs must be received at the contracting office by the same specific common "cut-off" date for all offerors.

d. Pre-award Site Visits

Site visits may be necessary to asses information regarding certain offerors' capabilities, resources, organization, physical facilities, etc., to verify the offeror's proposal in the areas deemed necessary, and to clarify necessary proposal details unfamiliar to evaluators and staff. Not all offerors must be site visited.

Contract specialists (CSs) should conduct site visits together with appropriate program staff. CO/CSs are responsible for conducting and documenting site visit and oral discussions, although program staff take the lead in conducting and documenting technical aspects of the proceedings, including selection of appropriate scientific or technical consultant reviewers to participate in the site visit. These may include TEG members. Reports from individual reviewers should be provided to the CS or technical designee for preparation of a site visit report.

6. Consideration for Award

a. Final Evaluation/recommendations

After best-and final offers are received, the CO and PO subject them to a final evaluation

of technical, cost/price, and other salient factors, assisted by a Source selection Panel (SSP) as necessary. The SSP, including a recorder, is appointed by the CO, utilizing recommendations from the PO.

The SSP's final evaluations must apply the same criteria for final evaluations of BAFOs as those used in the technical evaluation of proposals, and any other factors announced in the RFP. New information obtained during discussions may provide sufficient justification to rescore some evaluation criteria. Based on these considerations, the SSP shall establish a final ranking.

b. Contractor Selection

The SSP recommends in writing to the CO which source(S) it judges can perform the contract in a manner most advantageous to the Government, price and other factors considered as described in the RFP, and should therefore be selected for award(s). the CO has final authority for selection.

Special program constraints may be considered in selection, e.g., needs for geographical distribution, different population mixes in clinical studies, or different technical approaches to a problem, provided the RFP made those factors known.

In all cases, contract files must document the rationale for award decisions. debriefings are generally conducted after contract award when requested by individual unsuccessful offeror. [See regulations specified in 6.a., above.]

After receiving BAFOs and selecting successful offeror(s) for award(s), the CO, in coordination with the PO, determines limited touchup negotiation objectives, if required.

c. touch up Negotiations

The Co-may conduct limited touch up negotiations with the selected source(s) (HHSAR 315.670). Program staff generally assist the CO in any aspects of negotiations relating to technical performance requirements. See F.1.d. for special clearances before contract award.

G. Procedures: Acquisitions by Other than Full and Open Competition:

While this chapter emphasizes competitive solicitations, review and evaluation principles above apply generally to both solicited and unsolicited proposals obtained by other than full and open competition. Some differences exist in the way those proposals are handled, however, since protecting the integrity of the competitive process is no an issue. However, staff are reminded of the confidential nature of the information, the Procurement Integrity prohibitions, and the prohibition against disclosing proprietary information. Guidance for processing a Justification for other than Full and Open Competition (JOFOC) is contained in the DCG JOFOC Desk Guide.

1. Solicited Proposals

a. NEW

When the NIH solicits a contract proposal directly from a source without competition, it must establish that the source is the only one that can realistically perform the specific requirement, and that the solicitation is otherwise justified within the FAR and HHS regulations governing JOFOCS. Peer reviews for R&D project concepts and proposals are required as for competitive proposals (see 42 CFR 52h. 10 and this chapter, F.1 and F.2, above).

Since competitive selection of sources based on uniform evaluation criteria does not apply, the RFP need not include formal criteria. these are useful, however, both to offerors in preparing proposals to meet NIH requirements, and to technical evaluators in assessing sources' corresponding abilities. When the RFP contains no formal evaluation criteria, technical evaluators will concentrate on scientific-technical methodology, offeror organizational or staff qualifications and resources, and other factors relevant to the source's ability to meet the contract requirements.

b. Extensions

With certain exceptions, extensions of existing contracts also must be approved within HHS acquisition guidelines before proposals are solicited without competition. Extensions may aim to continue or complete work on the same project, or, as noted in c below, may introduce expanded or changed approaches or subject matter.

Extensions to continue contract work/effort under awarded cost-reimbursement completion contracts do not require justifications for other than full and open competition, provided that previous concept reviews defined those efforts. extensions to allow additional time and/or effort on term for/ level-of-effort contracts do require noncompetitive approval within HHS guidelines, however.

In addition, extensions for expansions or changes in work may require prior concept peer reviews, depending on the circumstances. (see the chapter, F.1.a., above.)

Scientific peer review is not required to evaluate proposals to extend R&D contracts to complete previously peer-reviewed and approved project targets or goals or approaches. For those, adequate scientific evaluation of proposals must nonetheless be performed by competent review groups; however, this may not include staff with selection, award, or administrative responsibilities or involvement with pertinent projects or awards.

c. Additions or Expansions

Scientific peer reviews and approvals of proposals, i.e., "acceptable" recommendations, are required for significant new work and costs to be added to existing contracts, e.g., revised/ expanded statements of work, and all JOFOC situations.

2. Unsolicited Proposals

Unsolicited contract proposals are those submitted in writing without prior formal NIH initiative or solicitation. FAR 15.506 and HHSAR 315.5 establish procedures to determine whether unsolicited proposals should receive comprehensive evaluation.

Staff shall return unsolicited proposals to the offerors, citing reasons, when their substance:

is not related to the program's mission or is not of programmatic interest

is available to the Government without restriction from another source;

closely resembles a pending competitive acquisition requirement; or

has major deficiencies in content so that an adequate scientific review is not possible.

does not demonstrate an innovative and unique method, approach, or concept.

If it is determined that comprehensive evaluation is warranted, both the project concept and approaches must receive scientific peer review evaluation by at least three or more experts.

It is essential that evaluators of unsolicited contract proposals consider these factors, in addition to any others appropriate for the particular proposal, in making their conclusions and recommendations:

a. unique and innovative methods, approaches or concepts demonstrated by the proposal.

b. potential contributions of the proposed effort to specific program objectives;

c. overall scientific-technical significance, originality and merits of the proposed project;

d. adequate methodology to conduct the research;

e. qualifications, capabilities and experience of the proposed principal investigator, team leader, or key staff who are critical in achieving the proposal objectives;

f. the offeror's capabilities, related experience, resources, facilities, techniques, or unique combination of these which are integral factors for achieving the proposal objectives and which are available.

g. reasonableness of proposed costs and duration.

If the proposal receives a favorable scientific peer evaluation, award may be made without competition provided the JOFOC has been approved and other essential requirements are completed. Any unique aspects of the above evaluation factors may be helpful in determining if award without competition is justified.

H. Additional Information:

Further information on this Manual chapter, and advice on generic issues and specific questions regarding contract project and proposal review and award processes may be obtained from:

for scientific-technical-programmatic content-Extramural Program Management Office, OEP, OER, at 496-4716; and

for contract-business management content- Acquisition Policy and Procedure Branch, DCG, OA, at 496-6014.

I. Additional Copies:

For copies of this Manual chapter, complete and send a Form NIH 414-5, "Request for Manual Chapter," to the Printing and Reproduction Branch, DTS, Building 31, ROOM B4B-N-09; or call the Extramural Programs Management Office on 496-4716 for single copies.

Appendix 1. Sequence of Steps in the Development of Projects and Review of New Competing R&D Contract Proposals:

Project Concept Development

Concept Peer Review

Acquisition Plan/Request for Contract

Request for Proposals

Receipt of Proposals

Technical Evaluation

Preliminary Cost Analysis

Evaluation Reports

Source Evaluation Panel

Competitive Range Determination

Competitive Range Discussions Site Visits if necessary

Detailed Cost Analysis

Negotiation Plan

Final Negotiations

Best and Final Offers

Source Selection Panel

Source Selection

Special Considerations

Contract Award

Appendix 2. Sample Introductory Statement for R&D Contract Project Concept Review Meetings:

1. This meeting has been (planned/announced) to be open to the public and will be held in open session so long as advisory (committee/group) discussions of proposed contract project concept involve only general project purposes, scopes, and goal, and various optional approaches to obtain the kinds of (findings/results) we seek.

2. The meeting will be open to the public; however, if the concept discussions turn to the development or selection of details of the projects or RFPs, such as specific technical approaches, protocols, statements of work, data formats, or product specifications, the meeting will be closed. Closing the session is intended to protect the free exchange of the advisory group member' opinions and to avoid premature release of details of proposed contract project or RFPs. (ref. 45 CFR 11.5 (a)(6)(ii)(c)) Also, (committee/group members have been cautioned that if they participate in or attend in those situations, they, their spouses, parents, children, close professional associates, and their organizations will be ineligible to receive a contract based on a subsequent request for proposals. (ref. 42 CFR 52h.5(b)(3))

   (A variant on the second paragraph may be used to start closed sessions held to discuss specifically the kinds of details outlined. As for all meetings, the advisors should have been cautioned beforehand, and no public attendance should be invited.)